The passage of the 21st Century Cures Act ("Cures Act") and revisions to the Common Rule (45 CFR Part 46) ("Common Rule") in the last year mandated significant changes to informed consent laws. As a result of these changes, sponsors of research ("Sponsors"), institutions conducting research ("Institutions"), and the institutional review boards ("IRBs") approving research will need to review policies and practices involving informed consent. As explained below, a recently published FDA guidance document makes a first step toward implementing some of these changes by permitting waiver of certain consent requirements for low risk research involving human subjects. Additionally, a recent ruling by the Pennsylvania Supreme Court discussed below reminds investigators, Institutions, and Sponsors performing clinical research in Pennsylvania that state informed consent laws and common law must also be considered before conducting clinical research involving human subjects. The following brief discussion provides some insight into how Sponsors, Institutions, and IRBs should take into account varying sources of law when determining when to require consent for research involving human subjects.

FDA Guidance on Waivers of Consent

On July 13, the United States Food and Drug Administration ("FDA") issued a guidance document titled “IRB Waiver on Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects” ("Consent Guidance"). The Consent Guidance states that “FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements” to the extent that the IRB documents that: the research “involves no more than minimal risk;” the waiver “will not adversely affect the rights and welfare of the subjects;” the research “could not practicably be carried out without the waiver;” and “subjects will be provided with additional pertinent information after participation,” if appropriate. The Consent Guidance is an initial step toward implementing Section 3024 of the Cures Act, which amended the Food, Drugs, and Cosmetic Act to provide FDA with the authority to exempt certain research of drugs or medical devices from informed consent requirements if the research poses “no more than minimal risk” to human subjects and includes “appropriate safeguards to protect the rights, safety, and welfare” for participating subjects. However, current FDA regulations do not provide IRBs with the power to waive consent except in certain circumstances involving an emergency or a life-threatening situation. While FDA's guidance documents contain disclaimers that the documents, themselves, lack any authority and cannot be relied upon, Sponsors, Institutions, and IRBs should be confident moving forward under the Consent Guidance as it stems directly from authority granted to FDA under the Cures Act and is consistent with the approach taken by the revised Common Rule. The FDA is expected to provide updates to its own human research subject protection regulations in 21 CFR Parts 50 and 56, which based on the Consent Guidance will include “minimal research” provisions similar to the Consent Guidance and the revised Common Rule. These rules will also address new provisions regarding identifiable biospecimens, which are not addressed under the Consent Guidance. Once these new rules are established, FDA has stated that it will withdraw the Consent Guidance.

Recent Case Law

While Federal laws and regulations shape many aspects of informed consent, state laws may impose additional
nuances that providers must understand. For example, a recent decision by the Pennsylvania Supreme Court will impact the manner in which informed consent must be obtained by physicians practicing in the state of Pennsylvania. In *Shinal v. Toms, M.D.*, 162 A.3d 429 (2017), Court held that physicians may no longer rely upon information provided by non-physicians to satisfy physician obligations under the MCARE Act, 40 Pa. Stat. § 1303, et seq, which imposes a duty on physicians to obtain informed consent before performing certain procedures. The specific law at issue was Section 504 of the MCARE Act, which creates a duty for a physician “to a patient to obtain the informed consent of the patient” before performing surgery, administering radiation or chemotherapy, administering a blood transfusion, inserting a surgical device, or “administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.” In *Shinal v. Toms, M.D.*, 162 A.3d 429 (2017), the plaintiff asserted that Section 504 required Dr. Toms, the plaintiff’s surgeon, to provide all information and receive a patient’s informed consent personally in order to fulfill the physician's duty for obtaining informed consent under the statute. After an initial discussion with Dr. Toms regarding certain surgical options, the plaintiff later called to ask additional questions regarding different surgical procedures and was directed to a nurse to have her questions answered. The plaintiff argued that her consent for the surgery was not sufficiently informed because the information provided to her about her surgical options should have been provided by Dr. Toms. The Court agreed, and its 4-3 decision held that physicians in Pennsylvania must directly “disclose the information required to obtain informed consent.”

While *Shinal* involved consent for a surgical procedure, Section 504 of the MCARE Act also requires physicians to obtain informed consent before administering an experimental drug or device. This ruling will undoubtedly require many Institutions in Pennsylvania to change how informed consent is obtained from potential subjects in clinical trials, as it is common practice within the industry for physician investigators to delegate the informed consent process, or at least certain portions of the consent discussion with potential research subjects, to members of the Institution's study staff. Sponsors will likewise want to investigate the consent processes of Institutions conducting research on their behalf in Pennsylvania and review informed consent templates used by these Institutions to ensure they reflect the holding in *Shinal*.

The position express by the *Shinal* Court that only information provided by a licensed physician may be considered in determining whether the physician fulfilled his or her duty to provide informed consent appears to be unique among the states. Nevertheless, it demonstrates to Sponsors, Institutions, and IRBs the importance of looking beyond FDA regulations and the Common Rule when developing and maintaining standard operating procedures and templates for obtaining informed consent. Even if certain research may meet “minimal risk” rules at a federal level, Institutions must still abide by applicable state laws with regard to the requisite consent required before treating patients within the study.

©2019 Epstein Becker & Green, P.C. All rights reserved.